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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Kimberly A. Gillis et al. Application No.: 09/996,529 Confirmation No. 3553 Filed: November 28, 2001 For: Expression Analysis of Inhibitor of Differentiation Nucleic Acids and Polypeptides Useful In the Diagnosis and Treatment of Prostate Cancer Attorney Docket No.: 102729-14	Group Art Unit: 1642 Examiner: Davis, Minh Tam B.

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Dear Sir:

I enclose herewith for filing in the above-identified application the following:

1. Response to Restriction/Election Requirement; and
2. Return receipt postcard.

The Commissioner is authorized to charge any overpayments or underpayments if necessary to our Deposit Account No. 141449, Reference No. 102729-14, Customer No. 021125. A duplicate of this sheet is enclosed.

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March 16, 2004
Date

Thomas Engellenner, Reg. No 28,711

Respectfully submitted,

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16 March 2004		By:
Date of Signature and Mail Deposit		Thomas J. Engellenner Reg. No. 28,711

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION/ELECTION REQUIREMENT

Dear Sir:

In the Office Action mailed from the Patent Office on February 17, 2004, the Examiner required election of one of the following 34 patentably distinct groups:

Groups 1-3: Claims 1-7, 11-16; Class 435, subclass 6.

Method detecting prostate cancer by measuring mRNA level or ID1 or ID3 marker or combination

Groups 4-6: Claims 1, 3-10; Class 435, subclass 7.1.

Method of detecting prostate cancer by measuring protein level of ID1 or ID3 marker or combination

Groups 7-9: Claims 17-21; Class 435, subclass 6.

Method of monitoring progression of prostate cancer by measuring mRNA level of ID1 or ID3 marker or combination.

Groups 10-12: Claims 17, 19-21; Class 435, subclass 7.1.

Method of monitoring progression of prostate cancer by measuring protein level of ID1 or ID3 marker or combination.

Groups 13-14: Claims 22, 35; Class 435, subclass 6.

Method of assessing efficacy of treating prostate cancer by measuring mRNA level of ID1 or ID3 marker.

Groups 15-16: Claims 22, 35; Class 435, subclass 7.1.

Method of assessing efficacy of treating prostate cancer by measuring protein level of ID1 or ID3 marker.

Groups 17-18: Claim 23: Class 435, subclass 6.

Method of assessing the potential of a test compound to trigger prostate cancer by measuring mRNA level of ID1 or ID3 marker.

Groups 19-20: Claim 23: Class 435, subclass 7.1.

Method of assessing the potential of a test compound to trigger prostate cancer by measuring protein level of ID1 or ID3 marker.

Groups 21-22: Claim 24: Class 514, subclass 2.

Method for treating prostate cancer by administering ID1 or ID3 protein.

Groups 23-24: Claim 25: Class 514, subclass 44.

Method for treating prostate cancer by expressing ID1 or ID3 protein by an expression vector.

Groups 25-26: Claims 26-27, 29: Class 435, subclass 6.

Method for identifying a compound useful for treating prostate cancer by measuring the mRNA level of ID1 or ID3 markers in the presence or absence of the compound.

Groups 27-28: Claims 26, 28-29: Class 435, subclass 7.1.

Method for identifying a compound useful for treating prostate cancer by measuring the protein level of ID1 or ID3 markers in the presence or absence of the compound.

Groups 29-30: Claims 30-31: Class 435, subclass 7.1.

Method for identifying a compound useful for treating prostate cancer by measuring the activity of ID1 or ID3 markers in the presence or absence of the compound.

Groups 31-32: Claims 32-33: Class 514, subclass 44.

Method for treating prostate cancer comprising administering a compound which increases the mRNA level of ID1 or ID3.

Groups 33-34: Claims 32, 34: Class 514, subclass 44.

Method for treating prostate cancer by administering a compound which increases the protein level of ID1 or ID3.

Applicants respectfully traverse the restriction requirement as improper. However, for the purpose of being responsive to the instant Office Action, Applicants hereby elect the Group 3 claims 1-7 and 11-16 (drawn to methods of detecting prostate cancer by measuring mRNA level of a combination of the ID1 and ID3 markers) with traverse.

Applicants' invention is directed to using Inhibitor of Differentiation (ID) markers, *e.g.,* ID-1 and ID-3, as genetic markers for the detection, diagnosis and prognosis of prostate disorders. The invention provides methods and screening assays for the detection and diagnosis of prostate cancer, as well as for testing for compounds that effect the expression levels of ID proteins in prostate cancer.

Applicants have presented generic linking claims 1, 17, 22, 23, 24, 26, 32, and 35, directed to the ID markers that exhibit an altered expression associated with prostate cancer. The Examiner concedes that linking claims are presented. Thus, upon allowance of a linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn with regard to any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s).

For the sake of clarity, the following arguments will be presented based on the different groups outlined in the Restriction Requirement. The Restriction Requirement has separated the various claims into groups with claims directed to the *mRNA* level of the ID markers, in class 435, subclass 6 (Groups 1-3, 7-9, 13-14, 17-18, 25-26), groups that determine the *protein* level of the ID

markers, in class 435, subclass 7.1 (Groups 4-6, 10-12, 15-16, 19-20, 27-30), groups with claims directed at treating prostate cancer, in class 514, subclass 44 (Groups 23-24 and 31-34), and groups with claims directed at treating prostate cancer by administering ID1 or ID3 (Groups 21-22). Furthermore, the Restriction Requirement states, at page 9, that:

> "Inventions 1-34 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success."

Reconsideration and withdrawal of the restriction requirement is requested. The invention is drawn to measuring the expression levels of ID proteins (e.g., ID1 and/or ID3) associated with prostate cancer. The expression level can be monitored by *either* measuring the nucleic acids associated with ID (e.g., RNA, or DNA), or the ID protein levels. The MPEP 803.04 states that "nucleotide sequences encoding the same protein are ***not*** considered to be independent and distinct inventions and will continue to be ***examined together***." Accordingly, the Examiner is requested to withdraw the restriction requirement such that mRNA and protein of the ID1 and ID3 are examined together in this application.

In addition, the Applicants further disagree that with restrictions imposed by the Examiner in that they split up the two markers, ID1 and ID3, of the claimed invention. The screening methods described by the invention encompass both markers, individually and in combination. Forcing an election between the two markers, ID1 and ID3, is totally unnecessary. According to MPEP 803.04:

> "the Commissioner has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See *Examination of Patent Applications Containing Nucleotide Sequences,* 1192 O.G. 68 (November 19, 1996). It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction." (Emphasis added.)

Thus, Applicants urge the Examiner to amend the groups such that the both markers ID1 and ID3 are examined in this application.

The Examiner has taken a position, which is contrary to MPEP 803.04, that methods and reagents required to detect proteins are different from those required to detect nucleic acids.

Applicants believe that this grouping is improper. Nonetheless, in order to be responsive to this Office Action, Applicants respond to this improper grouping by stating that a more appropriate grouping should be based on methods for detecting nucleic acids as being patentably distinct from methods for detecting proteins. With this in mind, claims 1, 3-10 (Groups 4-6), claims 17, 19-21 (Groups 10-12), claims 22, 35 (Groups 15-16), claim 23 (Groups 19-20), and claims 26, 28-29 (Groups 27-30) all of which are in class 435, subclass 7.1, and should be grouped together as being directed to measuring *proteins*. Furthermore, claims 1-7, 11-16 (Groups 1-3), claims 17-21 (Groups 7-9), claims 22, 35 (Groups 13-14), claim 23 (Groups 17-18), and claims 26-27, 29 Groups 25-26) are all in class 435, subclass 435, subclass 6, and should be grouped together as being directed to measuring *nucleic acids*. In addition, claim 25 (Groups 23-24), claims 32-33 (Groups 31-32), and claims 32, 34 (Groups 33-34) are all in class 514, subclass 44 and should be grouped together as being directed to methods of treating prostate cancer. Moreover, claims 32-33 (Groups 31-32) also involve measuring *nucleic acids*, and as such should be grouped with all claims directed to detecting nucleic acids.

This is a more appropriate grouping because, for example, the methods and reagents required to detect the expression of ID nucleic acids to assess whether a subject is afflicted with prostate cancer (Group 25-48), are the *same methods and reagents* required to detect prostate cancer (Groups 1-3), to monitor the progression of prostate cancer (Groups 7-9), to assess the efficacy of treating prostate cancer (Groups 13-14), to assess the potential of a test compound to trigger prostate cancer (Groups 17-19), and to identify a compound useful for treating prostate cancer (Groups 25-26). Despite the fact that there are different objectives, e.g., some claims involve incubating the sample with test compounds and observing the effects of such compounds on ID nucleic acid expression levels, the ultimate methods and reagents for detecting the effects of such compounds *remains the same*. That is to say that, irrelevant of whether the expression levels of nucleic acids associated with ID are measured in the presence or absence of a test compound, the expression levels will nevertheless, still be measured using the same reagents to detect the nucleic acids (e.g., reverse transcriptase-PCR).

Furthermore, it is conceded in the Restriction Requirement that Groups 1-3, 7-9, 13-14, 17-18, and 25-26 belong to the same class/subclass of 435/6. Thus, searching for Groups 1-3 invention will inherently also involve search for Groups 7-9, 13-14, 17-18, and 25-26 inventions.

Accordingly, a single search would suffice for claims 1-7, 11-16 (Groups 1-3), claims 17-21 (Groups 7-9), claims 22, 35 (Groups 13-14), claim 23 (Groups 17-18), and claims 26-27, 29 Groups 25-26) and thus it would not be a serious burden on the Examiner to search all of the groups relating to *nucleic acids* together (class/subclass of 435/6).

The Examiner is urged to call the undersigned at the telephone number indicated below so that any remaining issues can be discussed.

Respectfully submitted,
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Date: 16 March 2004

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